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Jonathan P. O'Brien, Ph.D.
Honigman Miller Schwartz and Cohn
350 East Michigan Avenue
Suite 300
KALAMAZOO, MI 49007

EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,738	HILFINGER ET AL.	
	Examiner	Art Unit	
	Richard Schnizer	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-16,19,20,22,24 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-16, 19, 20, 22, 24, and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

An amendment was received and entered on 12/31/09.

Claims 26 and 27 were canceled.

Claims 8-16, 19, 20, 22, 24, and 30 remain pending and are under consideration.

Rejections and objections not reiterated from the previous Office Action are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 10-15, 19, 20, 22, 24, 26, 27, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niedzinski et al (Lipids 35(7): 721-727, 2000), Keener et al (US Patent 6,627,197), Gebeyehu et al (US Patent 6,075,012), Mahato et al (6,875,611), and Wu et al (US 5166320).

Niedzinski taught cholic acid conjugates comprising a substituted alkyl polyamine DNA binding domain and their use to protect DNA from degradation in the gastric system. Niedzinski envisioned the use of these conjugates to deliver therapeutic nucleic acids by oral delivery to the gastrointestinal system, particularly to the enterohepatic receptors of the small intestine, which recognize and take up bile salts. See abstract, paragraph bridging pages 721 and 722. The cholic acid moieties were esterified through an oxygen at C3 to a DNA binding domain. See scheme 1 on page 722, compounds 5 and 6. Niedzinski showed the conjugates could be used to deliver plasmids to non-gastric cells, i.e. NIH 3T3 fibroblasts (see paragraph bridging pages 725 and 726, and Fig 5 on page 726).

Niedzinski did not teach the use of cholestanol, coprostanol, glycocholic acid, chenodeoxycholic acid, deoxycholic acid, glycochenodeoxycholic acid, taurocholic acid, or taurochenodeoxycholic acid. However, Niedzinski considered his conjugation technique to be applicable to a variety of bile acids through the C3 hydroxyl (see last sentence of column 1 on page 724). Niedzinski also did not teach DNA binding domains comprising peptides.

Keener taught the use of bile acids, and cholesterol derivatives generally, as hydrophobic conjugates to aid in the cellular entry of a conjugated peptide (a proricin variant). Proricin is hydrophilic and so does not readily traverse cell membranes. Keener overcame this problem by conjugation of a hydrophobic moiety, such as a sterol or bile acid, that facilitates traversal of the cell membrane. Disclosed hydrophobic groups included bile acids and cholesterol derivatives such as cholic acid, coprostanol,

glycocholic acid, chenodeoxycholic acid, deoxycholic acid, glycochenodeoxycholic acid, and taurocholic acid. See abstract, column 4, lines 49-57, and column 19, lines 37-55.

Mahato taught cationic lipids for nucleic acid delivery comprising a sterol or bile acid hydrophobic group conjugated to a cationic protamine peptide. A variety of hydrophobic sterol or bile acid groups could be used. Illustrative sterols included cholestanol and coprostanol. Illustrative bile acids included glycoholic acid, chenodeoxycholic acid, deoxycholic acid, glycochenodeoxycholic acid, taurocholic acid, and the like. See column 2, lines 53-62. Note that Mahato also taught that the peptide can be attached to the sterol or bile acid by peptide bond (sentence bridging columns 2 and 3), so attachment via the N terminus of the peptide is also embraced. At column 6, lines 38-44, Mahato taught that a variety of linkages could be used to attach the peptide to the hydrophobic moiety, "which can be any of a variety of linkers known in the art for linking chemical subunits together into a whole unit, such amide linkages, including peptide linkages, urethane linkages, disulfide linkages, ether linkages, and the like." Representative complexes were formulated in 5% glucose. See column 12, lines 15-18. Mahato exemplified a nucleic acid encoding IL-12, which is a secreted protein, see column 3, lines 19-23; claim 34; and examples 6 and 7.

Thus it was clear to one of ordinary skill in the art at the time of the invention that bile acids and cholesterol derivatives were recognized as exchangeable, equivalent hydrophobic groups useful for facilitating the transfer of conjugated hydrophilic groups into cells.

Gebeyehu taught reagents and methods for intracellular delivery of nucleic acids. The reagents are cationic lipids with the general formula of ABZ, wherein A is a steroid such as the bile acid cholic acid, or the sterols stigmasterol or ergosterol, B is a linker, and Z can be a nucleic acid binding domain such as a substituted alkyl polyamine (Z_4-Z_8, column 7, lines 44-67) or a polycationic peptide (protamine, a histone, or other nucleic acid binding protein). See column 9, line 62 to column 10, line 10 first, then column 3, lines 50-64; column 4, lines 50-54; column 5, lines 36 and 52-58; and scheme 8 at columns 29 and 30. Accordingly, it was clear to those of ordinary skill in the art at the time of the invention that it was routine to conjugate nucleic acid binding domains to cholesterol derivatives to make nucleic acid delivery conjugates, and that substituted alkyl polyamines and polycationic nucleic acid binding peptides such as protamines and histones were exchangeable equivalent nucleic acid binding domains.

It would have been obvious to one of skill in the art at the time of the invention to substitute any hydrophobic bile acid or cholesterol derivative for the cholic acid of Niedzinski. One of ordinary skill at the time of the invention would have had a reasonable expectation that modified bile acids would be recognized and taken up by the appropriate receptors because Niedzinski taught that this occurred for C(3)-modified cholic acid. There is no reason of record to expect that other bile acids would not function similarly.

One of ordinary skill at the time of the invention would also have recognized that bile acids and sterols were recognized as functioning as hydrophobic moieties that can facilitate delivery of a conjugated hydrophilic moiety to cells. Thus it would have been

obvious to one of ordinary skill in the art at the time of the invention to substitute other bile acids and sterols for cholic acid in the conjugates of Niedzinski, inasmuch as one would reasonably expect these conjugates to be taken up by the enterohepatic receptors that normally function in uptake of bile acids, and to function as transfection-facilitating hydrophobic groups even in the absence of receptors.

One of ordinary skill would recognize from the teachings of Niedzinski, Keener, Mahato, and Gebeyehu that the hydrophobic nature of the bile acid and sterol conjugates would facilitate the traversal of lipid bilayers even in the absence of a bile acid receptor (as demonstrated by Niedzinski with NIH 3T3 cells). Hence one would have had a reasonable expectation of success in substituting these equivalent hydrophobic moieties for each other. MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. Furthermore, MPEP 2144.07 indicates that the selection of a known material based on its suitability for its intended use supports the determination of prima facie obviousness.

It would also have been obvious to one of ordinary skill in the art at the time of the invention to substitute a nucleic acid binding peptide, such as that taught by Mahato or Gebeyehu, for the nucleic acid binding polyamine of Niedzinski because these nucleic acid binding moieties were recognized in the art as equivalents in view of the

teachings of Gebeyehu, i.e. polyamines are equivalents of polycationic nucleic acid binding peptides. See MPEP 2144.06.

None of Niedzinski, Keener, Mahato, and Gebeyehu explicitly suggested a nucleic acid binding peptide that is a six amino acid chain of arginine.

Wu taught tissue-specific delivery of DNA using a conjugate of a polynucleic acid binding agent (such as polyarginine, protamine, histone, avidin, polylysine, or polyornithine) and a tissue receptor-specific protein ligand. See abstract, Fig. 1, and column 4, lines 39-44.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use polyarginine as a cationic nucleic acid binding peptide in view of the disclosure of Wu which demonstrates that those of skill in the art considered polyarginine to be an equivalent of the polycationic nucleic acid binding peptides disclosed by Mahato and Gebeyehu. i.e. protamine, histone, and polylysine. MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. In re Fout, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). See also the examples of rationales that can be used to support a prima facie case of obviousness, listed in the Federal Register, 2007, Vol. 72, No. 195, pages 56525-56534, especially rationales (A) and (B). Furthermore, MPEP 2144.07 indicates that the selection of a known material based on its suitability for its intended use supports the determination of prima facie

obviousness. There is no reason or evidence of record that would suggest that polycationic polyarginine would behave any differently than polycationic protamine, histone, or polylysine peptides when conjugated to a bile acid.

In the absence of evidence to the contrary, the length of the polyarginine chain does not receive patentable weight, since different lengths would be expected to perform equivalently. MPEP 2144.09 states that a prima facie case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. Compounds differing regularly by the successive addition of the same chemical group are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties.

Regarding claims 11 and 12, it would have been obvious to deliver the IL-12-encoding nucleic acid of Mahato using the composition of Niedzinski as modified above because Mahato demonstrates delivery of the nucleic acid using a similar compound, and because nucleic acid delivery is intended purpose of the compounds of Niedzinski.

Regarding claim 20 and the 'Y' linker peptide moiety, the first 2 or 3 amino acids of the DNA-binding peptide of Gebeyehu (histone, protamine or DNA binding protein) can arbitrarily be considered to be the linker peptide.

Regarding claim 30, the cited art did not explicitly teach a commercial package comprising the composition and instructions for use. However, Gebeyehu did teach kits comprising the compositions. See column 13, lines 18-24. It would have been obvious to one of ordinary skill in the art at the time of the invention to place the components of such a kit into a container. One would have been motivated to do so in order to organize

the components into an easily retrievable state. One would have been motivated to include instructions because one of ordinary skill in the art appreciates that referring to instructions decreases the frequency of errors. Thus the invention as a whole was prima facie obvious.

Thus the invention as a whole was prima facie obvious.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Niedzinski et al (Lipids 35(7): 721-727, 2000), Keener et al (US Patent 6,627,197), Mahato et al (6,875,611), Gebeyehu et al (US Patent 6,075,012) and Wu et al (US 5166320), as applied to claims 8, 10-15, 19, 20, 22, 24, 26, 27, and 30 above, and further in view of Perrie et al (J. Liposome Res. 12(1&2): 185-197, 2002).

Niedzinski, Keener, Mahato, Gebeyehu, and Wu render obvious methods of delivering nucleic acids to target cells of a subject by administering a nucleic acid encoding a protein and a lipidic agent comprising a bile acid or cholesterol derivative conjugated to a hexaarginine DNA-binding peptide. Niedzinski taught that the DNA/lipidic agent could be formulated with DOTAP and/or DOPE and also with DMDHP and DOPE. See paragraph bridging columns 1 and 2 on page 725, Table 2 on page 726, and Fig. 5 on page 726. Gebeyehu also suggested combination of steroid derived cationic lipids with lipids such as DOPE, DOSPA, DOTMA, or cholesterol for delivery to cells (see column 5, lines 37-45).

These references did not exemplify a composition comprising an antibiotic therapeutic compound.

Perrie taught oral intragastric delivery of cationic liposome comprising nucleic acids encoding the S (small) region of the hepatitis B surface antigen (HBsAg). DNA vaccines encoding HBsAg were formulated with a cationic lipid formulation (phosphatidylcholine/cholesterol/DOTAP) and administered orally. Immune responses against the antigen were observed. See abstract. The nucleic acid of Perrie is considered to be a therapeutic product that is antibiotic in nature by virtue of its activity in inducing an immune response against hepatitis B virus.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the conjugate of Niedzinski as modified by Keener and Gebeyehu to deliver any nucleic acid that one wished to express in a cell, regardless of the nature of the expressed protein, because the purpose of these conjugates is to deliver nucleic acids to cells. It would have been similarly obvious to use the conjugates of Niedzinski/Keener/Gebeyehu in the method of Perrie because Niedzinski and Gebeyehu taught that such conjugates could be added to cationic lipids such as DOTAP, and because the conjugate takes advantage of uptake by enterohepatic receptors. See Niedzinski at paragraph bridging columns 1 and 2 on page 725, and Table 2 on page 726, and Gebeyehu at column 5, lines 37-45. Further, Niedzinski showed in Fig. 5 that addition of a bile acid conjugate to a cationic lipid/cholesterol mixture improved transfection.

One of ordinary skill could consider the conjugates of Niedzinski, as modified by Keener and Gebeyehu, to be improved versions of the cholesterol of Perrie, i.e. versions that lend improved DNA binding and delivery characteristics, and would be

motivated to substitute them for, or add them to, the cholesterol of Perrie for that reason.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Niedzinski et al (Lipids 35(7): 721-727, 2000), Keener et al (US Patent 6,627,197), Mahato et al (6,875,611), Gebeyehu et al (US Patent 6,075,012) and Wu et al (US 5166320), as applied to claims 8, 10-15, 19, 20, 22, 24, 26, 27, and 30 above, and further in view of Kitadai et al (Brit. J. Cancer 81(14): 647-653, 1999).

Niedzinski, Keener, Mahato, and Gebeyehu render obvious methods of delivering nucleic acids to target cells of a subject by orally administering a nucleic acid encoding a protein and a lipidic agent comprising a bile acid or cholesterol derivative conjugated to a polyionic DNA-binding peptide. Niedzinski taught that the DNA/lipidic agent could be formulated with DOTAP and/or DOPE and also with DMDHP and DOPE. See paragraph bridging columns 1 and 2 on page 725, Table 2 on page 726, and Fig. 5 on page 726. Gebeyehu also suggested combination with lipids such as DOPE, DOSPA, DOTMA, or cholesterol for delivery to cells (see column 5, lines 37-45).

These references did not exemplify expression of a therapeutic antitumoral compound in vivo.

Kitadai taught transfection of human gastric carcinoma cells with an expression vector encoding the secreted protein interleukin-8. Transfection was performed using the cationic lipid formulation LIPOFECTIN (a 1:1 mixture of DOTMA and DOPE).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the conjugate of Niedzinski as modified by Keener and Gebeyehu to deliver any nucleic acid that one wished to express in a cell, regardless of the nature of the expressed protein, because the purpose of these conjugates is to deliver nucleic acids to cells.

It would also have been obvious to one of ordinary skill in the art at the time of the invention to use the bile acid conjugate of Niedzinski as modified by Keener and Gebeyehu in the method of Kitadai by adding it to the DOTMA/DOPE formulation (LIPOFECTIN) because Niedzinski taught that a similar conjugate could be effectively added to another DOPE/cationic lipid mixture to improve transfection (Fig. 5).

Also it would have been obvious to use a DOTAP/DOPE/conjugate mixture or a DMDHP/DOPE/conjugate mixture in place of the LIPOFECTIN in the method of Kitadai because such mixtures were intended for gene transfer to cells, and would be functional equivalents of LIPOFECTIN. MPEP 2144.06 indicates that when it is recognized in the art that elements of an invention can be substituted, one for the other, while retaining essential function, such elements are art-recognized equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. Furthermore, MPEP 2144.07 indicates that the selection of a known material based on its suitability for its intended use supports the determination of prima facie obviousness.

The nucleic acid of Kitadai is considered to be a therapeutic product that is an antitumoral.

Response to Arguments

Applicant's arguments filed 12/31/09 have been fully considered to the extent that they might apply to the new ground of rejection above, but they are not persuasive.

Applicant asserts that a polyarginine of six amino acids is "neither an art-recognized equivalent of nor performs equivalently to any other polyarginine, protamine, histone, or polylysine on the basis that the polyarginine-tailed compounds currently claimed do not have a predictable cell permeability as part of a complex with DNA across a range of 1-50 residues (Z)." This assertion is unpersuasive because it is not supported by any evidence. On the other hand, it is clear from the cited art that a wide variety of polycationic peptides can serve as nucleic acid binding peptides when conjugated to other molecules, including cholesterol derivatives. Thus one would have had a reasonable expectation of success in substituting any art recognized nucleic acid binding peptide for the nucleic acid binding moiety of Niedzinski. This includes the polyarginine peptide of Wu, which is not patentably distinct from the claimed 6 arginine peptide because compounds differing regularly by the successive addition of the same chemical group are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. See MPEP 2144.09.

Applicant asserts that the rejection fails to satisfy the test for prima facie obviousness of chemical matter used by the CAFC since *KSR*. Applicant alleges that the CAFC interpreted *KSR* to require an explicit showing of where the prior art

suggested making specific modifications necessary to achieve the claimed invention. Applicant relies on the findings of the court in *Takeda Chem. Indus., Ltd. V. Alphapharm Pty., Ltd.* Applicant asserts that the CAFC articulated that for a prima facie case of obviousness to be found for a chemical matter, "[i]n addition to structural similarity between compounds, a prima facie case of obviousness also requires a showing of 'adequate support in the prior art' for the change in structure". The current rejection meets this standard because it was clear from the cited art that a variety of nucleic acid binding peptides, such the peptide of Mahato and the peptides of Gebeyehu, could be conjugated to a variety of compounds, including cholesterol derivatives, while maintaining their function. Note that Wu suggested that a variety of nucleic acid binding peptides (polyarginine, protamine, histone, avidin, polylysine, or polyornithine) could be conjugated to a ligand in order to bind nucleic acids to a ligand for delivery. Thus it was clear from the prior art that those of skill were familiar with modular constructs comprising hydrophobic groups such as cholesterol derivatives, and/or ligands (such as proteins or cholesterol derivatives), conjugated to a variety of nucleic acid binding moieties including a variety of cationic peptides. Thus one of skill would have had a reasonable expectation of success in substituting one of these nucleic acid binding domains for another.

Applicant asserts that the court in Takeda made it clear that "in order to find a prima facie case of unpatentability in such instances, a showing that the 'prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention' was also required." This is not persuasive because the situation in

Takeda is not entirely analogous with the instant situation. In the instant situation, the prior art made clear that there was a variety of known nucleic acid binding peptides that were routinely attached to hydrophobic groups or ligands to serve an art recognized function. These peptides, including polyarginine, were viewed in the art as exchangeable, and there was a reasonable expectation of success in substituting one for the other. This situation did not exist in Takeda where the claimed molecule was not a modular compound with clearly defined functional regions that were viewed as exchangeable in the prior art.

Applicant asserts at page 11 of the response that the Examiner has asserted that all peptides are art recognized equivalents. This is incorrect. The Examiner has asserted that there exists a class of peptides that are known in the art to bind nucleic acids. Generally these peptides are polycationic. Wu discloses polyarginine, protamine, histone, polylysine, and polyornithine as examples. Gebeyehu exemplifies protamines and histones, and indicates that other nucleic acid binding proteins are acceptable. In view of these teachings one of skill would recognize that these peptides are members of a recognized class of exchangeable equivalents.

For these reasons the rejections are maintained.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Tracy Vivlemore, can be reached at (571) 272-2914. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Richard Schnizer/
Primary Examiner, Art Unit 1635